

### **REMARKS/ARGUMENTS**

Claims 1-2, 8, 11-13 16, 21, 24-26 and 46-50, 54-58 are pending. Claims 1, 48 and 50 have been amended herein, and claims 4-7, 10, 14-15, 17-19, 23, 51-53 and 59-61 have been cancelled herein.

To facilitate the issuance of this case, all claims withdrawn from consideration have been cancelled. Reconsideration is respectfully requested.

#### **1. Rejection of Claim 14 Under § 112**

Claim 14 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 14 has been cancelled, thus rendering this rejection moot.

#### **2. Rejection of Claims 1-2, 13, 16, 18, 21, 24-26, 48, 50 and 54 Under § 102(b)**

Claims 1-2, 13, 16, 18, 21, 24-26, 48, 50 and 54 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent 5,352,229 (Goble). Claim 18 has been cancelled.

Claim 1 as amended recites a supportive backing that combines the at least one through-hole, and the at least one attachment point extending from the front side of the backing in a non-orthogonal manner. This configuration combines a number of advantages. For example, the non-orthogonal orientation of the attachment point relative to the backing ensures tissue penetration and approximation stability (see specification, page 24, lines 3-16). Further, the at least one through hole provides a means for using a fastener to secure the backing to bone (see specification, page 51, lines 8-11).

In contrast, Goble discloses an arbor press staple and washer, which includes a flat plate 31, an opening 33 formed in the plate to allow threaded pin 24 to pass there-through, and a plurality of straight spikes 35/36 (Col. 5, line 55 to Col. 6, line 28; Fig. 2). The spikes engage the ligament by vertical movement of the plate 31 induced by threaded pin 24 (Col. 6, line 46 to Col. 7, line 4). The spikes extend from the plate 31 in an orthogonal manner so that the direction of the spikes match their movement. Opening 33 in plate 31 allows the pointed end of threaded

pin 24 to pass there-through and engage the ligament (Col. 5, lines 58-65). Staple 16 penetrates the bone, and is used to secure the plate 31 in place.

Goble does not teach or suggest the combination of a supportive backing and through-hole, with at least one attachment point extending from the backing in a non-orthogonal manner. This combination allows the present invention to engage and approximate tissue with a fastening device engaged through the through-hole, without constant externally applied forces used to maintain the tissue on the attachment point(s). More specifically, as shown in the figures of the present application, the attachment point(s) are angled away from the direction in which the tissue pulls, to ensure the tissue stays secured on the attachment point(s) simply by utilizing the tension supplied by the tissue itself. If the attachment points were to extend orthogonally as with the Goble device, then the tissue would too easily slide off the tines (without externally supplied forces, such as, for example, the forces supplied by complex staple 16, which pins the tissue against the bone material).

Therefore, Applicants respectfully submit that Goble does not teach or suggest the combination of claim 1. In fact, Goble teaches away from this combination because angling the spikes of Goble would be incompatible with the vertical movement of plate 31 as threaded pin 24 is operated.

Claims 2, 13, 16, 21, 24-26, 48, 50 and 54 depend upon claim 1, and are therefore deemed allowable for the reasons set forth above. Moreover, Goble fails to teach or suggest some of the elements in these dependent claims. For example, claim 48 (as amended) recites that the front and back sides are curved, and claim 50 recites the back side of the backing is concave. In contrast, the plate 31 in Goble is planar. On page 5 of the Office Action, the Examiner states that "there is some degree of concavity" seen in Fig. 2 of Goble. Not only is there no concavity seen by Applicants in Fig. 2, but Figs. 4 and 5 show side views of plate 31, clearly showing plate 31 as planar. Moreover, Goble expressly states that washer 30 "consists of a flat plate 31" (see col. 5, line 59).

It is therefore respectfully submitted that claims 1 (as amended), 2, 13, 16, 18, 21, 24-26, 48 (as amended), 50 (as amended) and 54 are allowable over Goble.

### **3. Rejection of Claims 11-12 and 55-58 Under § 103(a)**

Claims 11-12 and 55-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Goble. The Applicants respectfully traverse this rejection.

Claims 11-12 and 55-58 all depend from claim 1, which is considered allowable for the reasons set forth in Part 2 above. Additionally, claims 11 and 12 recite that the backing is porous material (such as mesh, net or lattice), and claims 55-57 recite the device comprises or is impregnated with at least one therapeutic agent (such as proteins, pharmaceuticals, or genetic material). Goble does not teach or suggest making washer 30 out of porous material or including therapeutic agents.

The Examiner concludes on page 6 that porous material is considered an equivalent of solid backing material. Applicants respectfully disagree and note the lack of any support for such a general conclusion. Deficiencies in the factual basis cannot be supplied by resorting to speculation or unsupported generalities. In re Warner, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967). The fact that claim 13 recites a solid backing material does not support a conclusion that the porous material recited in claim 11 is somehow equivalent. Likewise, there is no support for the general conclusion that it would have been obvious to add a therapeutic agent to the Goble device, as neither Goble or any other prior art is provided to teach or suggest this combination.<sup>1</sup> There must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984).

Therefore, claims 11-12 and 55-58 are deemed allowable over Goble.

---

<sup>1</sup> The Examiner appears to conclude that criticality of certain claimed elements is not established because, as stated in the specification, the feature "may" be included. The Applicant respectfully disagrees. The use of "may" in the

#### **4. Rejection of Claim 49 Under § 103(a)**

Claim 49 was rejected under 35 U.S.C. §103(a) as being unpatentable over Goble in view of US Patent 5,779,706 (Tschakaloff). The Applicants respectfully traverse this rejection.

Claim 49 depends from claim 1, which is considered allowable for the reasons set forth in Part 2 above. Additionally, there is no teaching, suggestion or motivation to combine the heating thermoplastic surgical system of Tschakaloff with the Goble device. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Carella v. Starlight Archery, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986). Because there is no such teaching, suggestion or incentive, the Applicants submit the present rejection is improper.<sup>2</sup>

#### **5. Rejection of Claims 1-2, 11-13, 18, 21, 24-26, 46-50 and 54-55 Under § 102(e)**

Claims 1-2, 11-13, 18, 21, 24-26, 46-50 and 54-55 were rejected under 35 U.S.C. §102(e) as being anticipated by US Patent 6,350,284 (Tormala). Claim 18 has been cancelled.

Claim 1 as amended recites a supportive backing that combines the at least one through-hole, and the at least one attachment point extending from the front side of the backing in a non-orthogonal manner. In contrast, Tormala teaches a biosorbable plate layer and a biosorbable web layer for treating cranial bone defects, attached with biosorbable screws 5. There are no attachment points extending from the Tormala device, let alone in a non-orthogonal manner.

The Examiner states on page 7 that “The web layer can be considered a point of attachment since it promoted growth.” The Applicants respectfully traverse this conclusion. The mere fact that the web layer promotes growth does not teach or suggest the attachment points as recited in claim 1, and the Applicants respectfully submit that it is improper to rely on an unsupported equivalency between two disparate elements such as attachment points (for approximating tissue) and a porous web layer (for promoting bone growth and healing).

---

specification merely acknowledges that not every novel and unobvious feature or combination disclosed in the specification need be included in every embodiment of the invention.

Claims 2, 11-13, 21, 24-26, 46-50 and 54-55 depend upon claim 1, and are therefore deemed allowable for the reasons set forth above. Moreover, Tormala fails to teach some of the elements of these dependent claims. For example, claims 11 and 12 recite the backing comprises porous material, such as mesh, net or lattice. In contrast, Tormala teaches that plate 2 (identified by Examiner as corresponding to the claimed supportive backing) is solid and stiff (see col. 2, line 57).

It is therefore respectfully submitted that claims 1 (as amended), 2, 11-13, 18, 21, 24-26, 46-50 and 54-55 are allowable over Tormala.

#### **6. Rejection of Claims 16 and 56-58 Under § 103(a)**

Claims 16 and 56-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tormala. The Applicants respectfully traverse this rejection.

Claims 16 and 56-58 all depend from claim 1, which is considered allowable for the reasons set forth in Part 2 above (Tormala clearly fails to teach or suggest attachment points extending from the backing). Additionally, claim 16 recites various configurations for the attachment point, none of which can be found in Tormala. Claims 56-58 recite a therapeutic agent impregnated or coated on the device, and the Examiner admits that Tormala does not explicitly recite such an agent. The Examiner concludes on page 11 such an agent would be obvious or inherent, yet recites no prior art teachings to support such a conclusion. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); MPEP 2143.01. Because the Examiner fails to cite prior art, and the requisite teaching/suggestion/motivation to combine the teachings of these references to result in the claim combination, the Applicants respectfully submit this rejection should be withdrawn.

---

<sup>2</sup> As stated above, the Applicant traverses the Examiner's conclusion that criticality of features is lacking simply because the specification describes the various features using the term "may".

It is therefore respectfully submitted that claims 16 and 56-58 are allowable over Tormala.

**7. Rejection of Claims 1-2, 4-8, 10-19, 21, 23-26 and 46-61 For Double Patenting**

Claims 1-2, 4-8, 10-19, 21, 23-26 and 46-61 stand rejected for obviousness-type double patenting over claims 1-7 and 412 of US Patent 6,645,226, and over claims 1,4,7,9-16 and 19 of US Patent 6,485,503. Claim 1 is further provisionally rejected for obviousness-type double patenting over claim 1 of copending application 10/299,119. Lastly, claims 1-2, 4-8, 10-19, 21, 23-26 and 46-61 stand provisionally rejected for obviousness-type double patenting over claims 1, 6 and 16 of copending application 10/418,325, and over claims 1, 4-5 and 8 of copending application 10/418,541.


Applications 10/299,119 and 10/418,325 have been abandoned. Terminal disclaimers for US. Patents 6,645,226 and 6,485,503, and copending application 10/418,541, is submitted herewith to overcome this rejection.

Appl. No.: 09/816,641  
Docket No.: 2502000-991130  
Response to Office Action of August 10, 2004

For the foregoing reasons, it is respectfully submitted that the present application is in condition for allowance.

Respectfully submitted,

GRAY CARY WARE & FREIDENRICH

Dated: Oct 20, 2004 By:   
Alan A. Limbach  
Reg. No. 39,749

Attorneys for Applicant(s)

Alan A. Limbach  
Gray Cary Ware & Freidenrich LLP  
2000 University Avenue  
East Palo Alto, CA 94303-2248  
650-833-2433 (Direct)  
650-833-2000 (Main)  
650-833-2001 (Facsimile)  
alimbach@graycary.com

Gray Cary\EM\7171789.1  
2502000-991130